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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: CHAPPEY *et al.*

Serial No.: 10/612,603

Filed: July 1, 2003 Examiner: Unassigned

For: COMPOSITIONS AND METHODS FOR DETERMINING THE SUSCEPTIBILITY OF A PATHOGENIC VIRUS TO PROTEASE INHIBITORS

Attorney Docket No.: 11068-065-999

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of :

☒ Each U.S. patent application publication and U.S. and foreign patent;

☒ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;

☐ all other information or portion which caused it to be listed on the PTO-1449.

1c. ☒ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.

2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

☒ Before the mailing of the first Office action on the merits;

☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.

3b. ☐ The $180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
☐ enclosed
☐ to be charged to Jones Day Deposit Account No. 503013.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The $180.00 fee set forth in 37 C.F.R. §1.17(p) is:
☐ enclosed.
☐ to be charged to Jones Day Deposit Account No. 503013.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).

6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.

7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)

7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .

8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

(Check Item 8a, 8b, or 8c)

8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.

8b. ☐ set forth in the application.

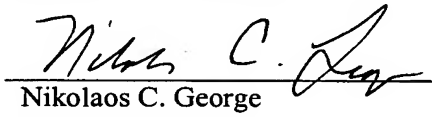
8c. ☐ enclosed as an attachment hereto.

9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 503013.

10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: May 19, 2004



39,201

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LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY DOCKET NO.	APPLICATION NO
11068-065-999	10/612,603
APPLICANT	
Chappey *et al.*	
FILING DATE	GROUP
July 1, 2003	1646

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	5,436,131	7/25/95	Condra *et al.*			
	A02	5,837,464	11/17/98	Capon *et al.*			
	A03	6,033,902	3/7/00	Haseltine *et al.*			
	A04	6,103,462	8/15/00	Paulous *et al.*			
	A05	6,242,187	6/5/01	Capon *et al.*			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	A06	WO99/67427	6/99	PCT				
	A07	Int'l Search Report for PCT/US03/21335	5/3/04	PCT				

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	A08	Condra *et al.*, (1996), "Genetic Correlates of In Vivo Resistance to Indinavir, a Human Immunodeficiency Virus Type 1 Protease Inhibitor ," *Journal of Virology*, 70(12): 8270-76
	A09	Genbank Accession Number AF324493 HIV-1 vector pNL4....[gi:12831134] (2001).
	A10	Gervaix *et al.*, (1997), "A New Reporter Cell Line to Monitor HIV Infection and Drug Susceptibility *in Vitro*," *Proc. Natl. Acad. Sci. USA* , 94:4653-4658.
	A11	Gong *et al.*, (2000), "In Vitro Resistance Profile of the Human Immunodeficiency Virus Type 1 Protease Inhibitor BMS-232632," *Antimicrobial Agents and Chemotherapy*, 44(9): 2319-26.
	A12	Gunthard *et al.*, (1998), "Comparative Performance of High-Density Oligonucleotide Sequencing and Dideoxynucleotide Sequencing of HIV Type 1 *pol* From Clinical Samples", *Aids Research and Human Retroviruses*, 14(10): 869-876..
	A13	Haubrich *et al.*, (2001), "CCTG 575: A Randomized. Prospective Study of Phenotype Testing Versus Standard of Care For Patients Failing Antiretroviral Therapy," *Antiviral Therapy*, 6(Supplement 1): 63.
	A14	Herrmann *et al.*, (1997), "A Working Hypotheses-Virus Resistance Development As An Indicator of Specific Antiviral Activity," *Ann. NY Acad Sciences*, 284: 632-637.
	A15	Hertogs *et al.*, (1998), "A Rapid Method for Simultaneous Detection of Phenotypic Resistance to Inhibitors of Protease and Reverse Transcriptase in Recombinant Human Immunodeficiency Virus Type 1 Isolates From Patients Treated with Antiretroviral Drugs," *Antimicrobial Agents and Chemotherapy*, 42(2): 269-276.
	A16	Hirsch *et al.*, (2000), "Antiretroviral Drug Resistance Testing in Adult HIV-1 Infection," *JAMA*, 283(18): 2417-26.
	A17	Katzenstein *et al.*, (2002), "Baseline Phenotypic Susceptibility and Virologic failure over 144 weeks Among Nucleoside RT Inhibitor Experienced Subjects in ACTG 364," Antiretroviral Drug Resistance Testing in Adult HIV-1 Infection," *2002 9th Conference on Retroviruses and Opportunistic Infections*, Session 77 Poster Session 591-T.
	A18	Katzenstein *et al.*, (2002), "The Inhibitory Quotient (IQ) for Saquinavir (SQV) Predicts Virologic Response to Salvage Therapy," *2002 9th Conference on Retroviruses and Opportunistic Infections*, Session 28 Poster Session 129.
	A19	Maguire *et al.*, (2002), "Emergence of Resistance to Protease Inhibitor Amprenavir in Human Immunodeficiency Virus Type 1-Infected Patients: Selection of Four Alternative Viral Protease Genotypes and Influence of Viral Susceptibility to Coadministered Reverse Transcriptase Nucleoside Inhibitors," *Antimicrobial Agents and Chemotherapy*, 46(3): 731-738.
	A20	Petropoulos *et al.*, (2000), "A Novel Phenotypic Drug Susceptibility Assay For Human Immunodeficiency Virus Type 1," *Antimicrobial Agents and Chemotherapy*, 44(4): 920-928.

	A21	Race *et al.*, (1999), "Analysis of HIV Cross-Resistance to Protease Inhibitors Using A Rapid Single-Cycle Recombinant Virus Assay For Patients Failing On Combination Therapies," *AIDS*, 13(15): 2061-2068.
	A22	Schuurman *et al.*, (1999), "Worldwide Evaluation of DNA Sequencing Approaches for Identification of Drug Resistance Mutations in the Human Immunodeficiency Virus Type 1 Reverse Transcriptase," *Journal of Clinical Microbiology*, 37(7): 2291-2296.
	A23	Shi *et al.*, (1997), "A Recombinant Retroviral System for Rapid In Vivo Analysis of Human Immunodeficiency Virus Type 1 Susceptibility to reverse Transcriptase Inhibitors," *Antimicrobial Agents and Chemotherapy*, 41(12): 2781-85.

EXAMINER	**DATE CONSIDERED**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.